



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/589,353

08/11/2006

Lennart Jonsson

08806.0193-00

8169

22852

7590

02/09/2009

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER
LLP

901 NEW YORK AVENUE, NW
WASHINGTON, DC 20001-4413

EXAMINER

DEAK, LESLIE R

ART UNIT

PAPER NUMBER

3761

MAIL DATE

DELIVERY MODE

02/09/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/589,353	Applicant(s) JONSSON ET AL.	
	Examiner LESLIE R. DEAK	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 August 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/11/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. Claims 9 and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
2. With regard to claim 9, Applicant claims that the “intended use” of the device “may be indicated by a specific resonance frequency.” It is unclear how this claim limits the structure of the claimed device. It is the position of the Examiner that any piece of matter comprises a specific resonance frequency, and, as such, the device disclosed by the prior art necessarily comprises a specific resonance frequency.
3. With regard to claim 23, Applicant claims that the sensor, transmitter, and receiver are located in “close” proximity to one another, but fails to provide any definition of “close.” It is unclear whether applicant means “close” to mean within inches, within the same room, within the same building, or even within the same town.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 3761

5. Claims 1-4, 9-11, and 13-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2004/0082867 A1 to Esch et al in view of US 6,272,903 to Crozafof et al.

In the specification and figures, Esch discloses the apparatus substantially as claimed by Applicant. With regard to claims 1, 3, 9, 13, and 17, Esch discloses a graft 1 for transporting biological fluid. The graft comprises a pressure sensor 2 that comprises a capacitive pressure sensor 20 and an inductive coil 30 that form an electric circuit (see paragraphs 0034, 0035). The inductive coil energizes the circuit, which measures a change in capacitance between the sensor and coil, which indicates a pressure change. The capacitance is measured by a second, external coil, which transmits the data to a controller 100 that is capable of performing data analysis (see paragraphs 0011, 0045).

Esch fails to specifically disclose that the pressure sensor is part of an extracorporeal circuit. However, Crozafof discloses a pressure measuring device that is placed on a tube that handles fluid flowing to and from the human body. (see paragraph 4-13). All of the elements of the claimed invention are known in the art, and it is the opinion of the Examiner that one having ordinary skill in the art at the time of invention could have combined the claimed elements (using the pressure sensor disclosed by Esch in the extracorporeal system disclosed by Crozafof) by known elements, yielding only the predictable result of an extracorporeal circuit with a pressure sensor.

With regard to claims 2 and 4, Esch discloses that in one embodiment, the capacitor comprises a split cylindrical capacitors comprising a trapped fluid (corresponding to applicant's compressible container) (see paragraph 0013).

With regard to claim 10, Esch discloses that the sensor may be embedded within the walls of graft 1 (see paragraph 0011).

With regard to claim 11, Esch discloses the use of one or more electrical fields to generate the pressure measurement.

With regard to claims 14 and 15, Esch and Crozafof disclose each structural element of the pressure sensor set forth in claim 1 – see rejection above.

Esch teaches that the pressure sensor may be integrated within the walls of the graft tube or placed outside the graft tube, but is silent as to the method of molding or attachment. The claimed phrases “wherein the device is insert molded” and “wherein the sensor is glued or welded to a wall” are being treated as product by process limitations; that is, that the pressure sensor is attached by the claimed methods. As set forth in MPEP 2113, product by process claims are NOT limited to the manipulations of the recited steps, only to the structure implied by the steps. Once a product appearing to be substantially the same or similar is found, a 35 U.S.C. 102/103 rejection may be made and the burden is shifted to applicant to show an unobvious difference. See MPEP 2113.

Thus, even though Esch is silent as to the process used to mount the pressure sensor to the tube, it appears that the product suggested by the prior art would be the same or similar as that claimed; especially since both applicant’s product and the prior art product is attached to a biological fluid tubing line.

With regard to claim 18, Applicant is setting forth the function of the claimed apparatus. It has been held that a recitation with respect to the manner in which a

Art Unit: 3761

claimed apparatus functions does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. See MPEP § 2114. In the instant case, it is the position of the Examiner that the controller disclosed by Esch is capable of being programmed to include an atmospheric pressure as a reference pressure, suggesting the limitations of the claims.

With regard to claims 16, 17, 19-21, Esch discloses that the graft is used to shunt blood for a dialysis procedure (see paragraph 0010), corresponding to Applicant's extracorporeal fluid management.

6. Claims 5-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2004/0082867 A1 to Esch et al in view of US 6,272,903 to Crozafof et al, further in view of US 5,756,900 to Arie et al.

In the specification and figures, the cited prior art suggests the apparatus substantially as claimed by Applicant (see rejections above), with the exception of a rigid box with a flexible membrane. Arie discloses a pressure sensing apparatus that is deployed on a tube that carries fluid. The sensor apparatus comprises a rigid metal box with a deflectable membrane 24 on one side (see Arie FIGS 1-3 and accompanying text). All of the elements of the claimed invention are known in the art, and it is the opinion of the Examiner that one having ordinary skill in the art at the time of invention could have combined the claimed elements (using the housing disclosed by Arie to hold the pressure-sensing capacitors disclosed by Esch in the extracorporeal system disclosed by Crozafof) by known elements, yielding only the predictable result of an extracorporeal circuit with a pressure sensor.

7. Claims 12, 22, 23 (as best understood), and 24-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2004/0082867 A1 to Esch et al in view of US 6,272,903 to Crozafon et al, further in view of US 5,807,258 to Cimochoowski et al.

In the specification and figures, the cited prior art suggests the apparatus substantially as claimed by Applicant (see rejections above), with the exception of using an RF signal to communicate between components. With regard to claims 22 and 28, Cimochoowski discloses an ultrasonic sensor for monitoring the pressure within a vascular graft, similar to the Esch device. The circuits include an RF coupling coil that transmits pressure information outside the patient's body. Use of RF simplifies the electronic circuitry that must be implanted in the patient (see Cimochoowski column 9, line 25 to column 10, line 15). Accordingly, it is the position of the Examiner that it would have been obvious to one having ordinary skill in the art to use RF signals as disclosed by Cimochoowski to relay pressure signals in the device suggested by Esch and Crozafon in order to allow for remote pressure monitoring.

With regard to claims 24-27, Esch and Crozafon disclose the use of the pressure measurement apparatus on extracorporeal circuits, including dialysis (see rejections above).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LESLIE R. DEAK whose telephone number is (571)272-4943. The examiner can normally be reached on Monday - Friday, 8:30am-5:00pm.

Art Unit: 3761

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leslie R. Deak/
Primary Examiner, Art Unit 3761
5 February 2009/Leslie R. Deak/
Primary Examiner, Art Unit 3761